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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/241,455 02/02/99 KRIVITSKI

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EXAMINER

QM22/0306

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ROCHESTER NY 14604

S7MAL, B

ART UNIT

PAPER NUMBER

3736

DATE MAILED:

03/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Applicant No.	Applicant(s)	
	09/241,455	KRIVITSKI, NIKOLAI M.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 29, 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-20 and 22-33 is/are rejected.
- 7) ☒ Claim(s) 8 and 21 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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Response to Arguments

1. After reviewing the Appeal Brief filed on December 29, 2000, it was determined that the claims are subject to new grounds of rejection.

2. In view of the appeal brief filed on December 29, 2000, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

- (a) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
- (b) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Rejections - 35 USC § 112

3. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 22 recites the limitation "the corrective produce" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

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The phrase "the corrective produce" should be "the corrective procedure".

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-7, 9-20 and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schneiderman in view of Quinn et al ('654).

In regards to claims 1, 9, 15, 16, 19, 20, 22 and 25, Schneiderman discloses the use of an angioplasty autoperfusion catheter flow measurement method and apparatus that further discloses the use of an angioplasty balloon for reducing a stenosis. Schneiderman also discloses the use of measuring blood flow through the use of an ultrasonic sensor. See Column 2, lines 10-46. In addition, Quinn et al discloses the use of a multi-parameter, multi-lumen catheter that further discloses: a blood property change port and a downstream sensor spaced apart from the port for producing a signal corresponding to a blood property; and a means connected to the sensor for calculating the flow rate corresponding to the signal from the downstream sensor. See Column 3, lines 48-60; Column 4, lines 60-67; Column 5, lines 1-7 and 38-48; Column 6, lines 59-67; and Column 7, lines 1-5. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method and apparatus of Schneiderman in view of

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Quinn et al to measure blood flow through the use of thermodilution, since the blood flow within a lumen can be measured by Doppler techniques as well as through thermodilution. It also would have been obvious to perform the blood flow measurement prior to and after the stenosis corrective procedure, since it would allow the cardiologist to determine if the stenosis has been effectively reduced to allow unimpeded blood flow. It would have been obvious to one of ordinary skill in the art to utilize a controller to calculate the blood flow, since the calculation would have to be performed utilizing data obtained from the sensor or sensors. The obtained data is efficiently analyzed through the use of a controller or computer, even though Quinn et al does not disclose the exact means of performing the calculation.

In regards to claims 2, 10 and 27, Schneiderman discloses the use of a blood property sensor placed within the lumen of the catheter inside the angioplasty balloon. See Figure 2. It would have been obvious to one of ordinary skill in the art to recognize that the sensor of Schneiderman is located such that it minimizes wall effects.

In regards to claims 3-7, 11-14, 23, 24 and 29-33, Quinn et al discloses the use of a means connected to the sensor for calculating the flow rate corresponding to the signal from the downstream sensor; the blood property change port includes an aperture for introducing a blood property variant; the blood property change port and sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow; the blood property change port includes a heat source for creating a local temperature gradient; the signal from the sensor corresponds to a blood flow in the vessel; a plurality of blood sensors are located

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in the blood vessel; the sensor detects changes in electrical resistance; and the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood. See Column 3, lines 48-60; Column 4, lines 60-67; Column 5, lines 1-7 and 38-48; Column 6, lines 59-67; and Column 7, lines 1-5. It would have been obvious to one of ordinary skill in the art to utilize a controller to calculate the blood flow, since the calculation would have to be performed utilizing data obtained from the sensor or sensors. The obtained data is efficiently analyzed through the use of a controller or computer, even though Quinn et al does not disclose the exact means of performing the calculation.

In regards to claim 17, even though Schneiderman and Quinn et al do not disclose the use of operating two separate catheters during the procedure, it is well known in the art to be able to operate within a body lumen utilizing several catheters, either within one another or placed on a guidewire.

In regards to claim 18, Schneiderman discloses the insertion of a catheter and a blood property sensor into a vessel includes inserting a catheter having a stenosis reducing member and a blood property sensor. See Column 2, lines 10-46.

In regards to claim 26, Schneiderman discloses the use of performing angioplasty to reduce the stenosis. See Column 2, lines 10-46.

In regards to claim 28, even though Schneiderman does not disclose rotating the sensor with respect to the vessel to reduce wall effects, it would have been obvious to one of ordinary

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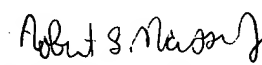
skill in the art to rotate the sensor when errant measurements were being received from the sensor.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter:

Claims 8 and 21 are allowable since they contain subject matter that is not disclosed in the prior art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758.


ROBERT L. NASSER
PRIMARY EXAMINER



BS

March 5, 2001